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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,989	05/25/2001	Jean-Louis Dasseux	9196-019-999	6407

24341 7590 02/10/2003

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EXAMINER
RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
1654	8

DATE MAILED: 02/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/865,989	DASSEUX ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/25/01, 3/15/02, and 10/16/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,16-18,25,33,40,50 and 53-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,16-18,25,33,40,50 and 53-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The Sequence Listing filed May 25, 2001 has been approved.

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The disclosure is objected to because of the following informalities: The Table Of Contents provided with the specification should be canceled because patents are not printed with page numbers. The status of the parent application in the claim for priority should be updated. At page 65, lines 4-6, the peptides designated SEQ ID NOS:229, 230, and 231 in the specification do not correspond to SEQ ID NOS:229, 230, and 231 as recited in the Sequence Listing filed May 25, 2001. It is suggested that the SEQ ID NOS in the specification be changed to SEQ ID NOS:230, 231, and 232, respectively. While there is a Table VII at page 95 of the specification and a Table IX at page 101 of the specification, the examiner was unable to locate a table numbered "VIII". In order to avoid the appearance that some section of the specification is missing should this application be issued as a patent, the tables need to be numbered consecutively, and any reference to the tables in the specification (e.g., numerous references to Table X occur throughout the specification) needs to be amended to reflect the new table numbering. Appropriate correction is required.

3. The following is a quotation of the first paragraph of 35 U S C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 16-18, 25, 33, 40, 50, and 53-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the claim limitations requiring all the residues present in the agonist compound to be D-enantiomeric residues (with the exception of glycine, which does not have a D- or L-configuration). Applicants point to page 44, lines 15-29, of the specification as support for the claim limitation. However, this section of the specification does not explicitly state, as is currently claimed, that all residues present in the agonist compound can be present in the D-configuration. Rather, this claim language appears to be an inference which Applicants are making from the "at least" language present at page 44, lines 20 and 26. Applicants' inference is not supported by the remainder of the specification. In particular, the immediately following paragraph, at page 44, line 30 - page 45, line 4, makes clear that Applicants did not contemplate a peptide comprised entirely of D-enantiomeric residues because such a peptide would not have been expected to form the alpha-helical peptides desired by Applicants. There is no original disclosure supporting the claim limitation of claim 1 that Z_1 can be RRN. The specification at page 50, line 17 - page 51, line 10, does not discuss a RRN blocking group. While a -NRR group is originally disclosed in conjunction with formulas (IV) and (V), this group is located in a different portion of the multimeric agonist than is the RRN group recited in instant claim 1. Applicants have not indicated where the original disclosure of the invention supports this new claim limitation. There is no original disclosure supporting the claim limitation of claim 1 that R can be a peptide having 5-7 residues. While page 49, line 29 - page 50, line 16, of the specification contains general language concerning extending the core peptides at their termini, this general language does not constitute a "full, clear, concise, and exact" description of the

specific numbers of residues now claimed by Applicants. Applicants have not indicated where the original disclosure of the invention supports this new claim limitation.

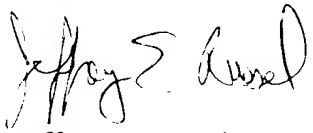
4. Claims 1, 16-18, 25, 33, 40, 50, and 53-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, part (i), line 1, recites a peptide length of 18 to 22 residues. However, given the presence of 18 residues in formula (I) plus the possible presence of up to 7 residues in R groups comprising Z_1 or Z_2, it appears that the peptide or peptide analogue of part (i) must comprise at least as many as 25 residues. Accordingly, claim 1, part (i), contains a contradiction as to the possible length of the peptide or peptide analogue. Claim 16 defines "HH" as being "a D-enantiomeric peptide or peptide analogue according to Claim 1". However, claim 1 uses the terminology "D-enantiomeric peptide or peptide analogue" only in conjunction with section (i). Accordingly, it is not clear if claim 16 embraces HH as being one of the deleted forms or altered forms of claim 1. For analogous reasons, claims 17, 18, 25, and 33 are also indefinite. There is no antecedent basis in the claims for the phrase "the ApoA-I agonist" in claims 40, 50, and 71. It is suggested that "compound" be inserted after "agonist" in claims 40, 50, 71, and 75 so that claim terminology is standardized. Claim 57 is indefinite because the residues specified for X_{18} are not basic residues as required by independent claim 1.

5. Parent patent U.S. 6,265,377 and related patent U.S. 6,037,323 have been carefully considered and are made of record, but their claims do not raise any obviousness-type double patenting issues with the instant claims.

U.S. Patent No. 6,004,925 and WO Patent Application 99/16459 are cited as art of interest, being available as prior art against the instant claims under 35 U.S.C. 102(e) and 102(a), respectively. These references teach peptide nos. 87, 96, 100, 107, and 174 which are comprised entirely of D-amino acids. However, these peptides do not have the sequence required by instant claim 1. Further, these references teach away from substituting significant numbers of the L-amino acids present with D-amino acids in their other disclosed peptides (see, e.g., column 27, lines 41-49, of U.S. Patent No. 6,004,925). Accordingly, the instant claims are deemed to be novel and unobvious over these two references

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
February 6, 2003